Amendments to the Specification

On page 2, please replace the paragraph starting on line 23 with the following:

An embodiment provides a method of controlling ablation volume depth during surface treatment of a target tissue site. The method includes providing a tissue surface treatment apparatus. The apparatus comprises a housing having a proximal end and a distal end including a tissue contacting surface having an aperture. The housing defines an interior with an energy delivery device positionable in the housing interior. The energy delivery device includes at least one electrode with a tissue penetrating distal end. The at least one electrode is configured to be advanced from the housing interior through the aperture and into a target tissue site to define an ablation volume at least partly bounded by the tissue surface. An advancement device is coupled to the energy delivery device. The advancement device is configured to advance the at least one electrode from the housing interior to a selected deployment depth. The tissue contact surface is positioned on a target tissue surface. The at least one electrode is advanced to a selected deployment depth beneath a tissue surface while avoiding a critical structure. Ablative energy is then delivered from the energy delivery device. An ablation volume is then created at a controlled depth below the tissue surface responsive to the electrode deployment depth while minimizing injury to the critical structure.

On page 3, please replace the paragraph starting on line 17 with the following:

Another embodiment of the invention provides a tissue surface treatment apparatus that includes a housing having a proximal end, a distal end including a tissue contacting surface and an interior defined by the housing. A handpiece is coupled to the housing. The tissue contact surface has a plurality of apertures. An energy delivery device including at least one electrode is positionable in the housing interior. The at least one electrode includes a tissue penetrating distal end in substantial alignment with an aperture of the plurality of apertures. The at least one electrode is configured to be advanced from the housing interior through the aperture and into a target tissue site to define an ablation volume at least partly bounded by the tissue surface. An advancement device is coupled to the energy delivery device. The advancement device is at least partly positionable within

at least one of the housing or the handpiece. The advancement device is configured to advance the at least one electrode from the housing interior into the target tissue site and completely withdraw~~al~~ the at least one electrode into the housing interior. A cable is coupled to one of the housing or the energy delivery device. The cable is configured to be coupled to an energy source.

On page 4, please replace the paragraph starting on line 9 with the following:

Still another embodiment of the invention includes a switching device coupled to at least one of the at least one electrode, a power supply coupled to the at least one electrode or a ground pad electrode coupled to the power supply. Impedance measurement circuitry is coupled to ~~the~~ at least one of the at least one electrode or the ground pad electrode. Logic resources are coupled to at least one of the impedance measurement circuitry or the switching device. The logic resources are configured to redirect at least a portion of a current flow going to the ground pad electrode responsive to an impedance change measured by the impedance measurement circuitry.

On page 4, please replace the paragraph starting on line 22 with the following:

~~Yet~~In yet another embodiment, the energy delivery device includes a first electrode and a second electrode. The first electrode is deployable to a first depth and a second electrode is deployable to a second depth independent of the first depth.

On page 5, please replace the paragraph starting on line 8 with the following:

Still yet another embodiment of the invention provides a tissue surface treatment apparatus that includes a housing having a proximal end, a distal end including a tissue contacting surface and interior ~~defining~~defined by the housing. A handpiece is coupled to the housing. A fluid delivery device is positionable in the housing interior. The fluid delivery device includes at least one hollow non-conducting infusion member with at least one infusion aperture and a tissue penetrating distal end. The at least one infusion member is configured to be advanced from the housing interior and into a target tissue site to infuse a fluid into tissue and define a tissue infusion volume. The fluid delivery device is configured

to be coupled to a fluid source. An advancement device is coupled to the fluid delivery device. The advancement device is at least partly positionable within at least one of the housing or the handpiece. The advancement device is configured to advance at least a portion of the at least one infusion member from the housing interior into the target tissue site and completely withdrawal the at least one infusion member into the housing interior. A conductor is coupled to at least one of the fluid delivery device or the at least one infusion member. The conductor is configured to be coupled to an energy source.

On page 10, please replace the paragraph starting on line 21 with the following:

Figures 44a-44c are schematic views illustrating configurations of the electrodes in bipolar embodiments of the invention. Figure 44a shows an embodiment with a single positive and negative electrode. Figure 44b shows a multiple positive electrodes in a circular pattern with a centrally located return electrode. Figure 44c shows an arc shaped pattern of positive electrodes with a single return electrode.

On page 15, please replace the paragraph starting on line 6 with the following:

Housing 12 can have a variety of shapes including rectangular, circular, oval and pyramidal. Referring to Figure 3, in a preferred embodiment housing 12 has a cylindrical shape, where the proximal and distal ends 12p and 12d comprise the two ends of the cylinder with a wall 12w. Ends 12p and 12d can be fixedly attached to the body of the cylinder 12b or can be movable therein which can include sliding and reciprocal movement. Housing 12 can be fabricated from a variety of polymers known in the art including rigid polymers, including but not limited to polycarbonate, acrylic, polyester, ABS and combinations thereof using injection molding or rim methods known in the art. Also housing 12 can be machined from both plastics and metals such as aluminum, stainless stealsteel and the like, using machining methods known in the art. Housing 12 can also be made from flexible metals such as or from compliant or resilient polymers that enable housing 12 to be flexible in one or more directions. Examples of flexible metals include, but are not limited to, nickel titanium alloys. Examples of resilient polymers include, but are not limited to, elastomers including silicone, polyurethane, PEBAX® and combinations thereof.

Flexibility of housing 12 can also be achieved through the use of an accordion or bellow construction of housing walls 12w. Also, in an embodiment all or portions of housing 12 can have transparent portions or viewing ports 12v made of transparent polymers such as polycarbonate so as to enable the physician to observe the tissue contacted by the housing as well as the position and advancement of the energy delivery devices there into. In use, this embodiment not only allows the physician to observe the tissue during placement of the housing 12, but also during the delivery of thermal energy to tissue site 5" and thus observe tissue blanching and other color changes indicative of the size of the developing ablation volume.

On page 16, please replace the paragraph starting on line 14 with the following:

For purposes of this application, an insulative coating is defined to be both an electrical and a thermal insulative coating. In a preferred embodiment, tissue contact surface 14 has an insulative coating 12ic that insulates against the transmission of RF energy. Coating 12ic can be made from electrically and thermally insulative polymers known in the art including, but not limited to, polyamide, polyamide fluorocarbons, PTFE and TEFLON®. Such coatings can range in thickness 12ct from 0.0001 to 0.1 inches with a preferred embodiment of 0.001 to 0.003 inches. Also in an embodiment, coating 12ic can be a ~~pealable~~peelable coating so as to be detachable or movable on housing 12, enabling the user to create a selectable insulative portion 12ip. Coating 12ic can be configured to be ~~pealable~~peelable and re-attachable using re-attachable, low strength adhesives known in the art.

On page 18, please replace the paragraph starting on line 12 with the following:

In use, a conformable or movable surface solves the problem of assuring and maintaining contact with an uneven or obstructed tissue surface before, during or after the ablation without causing undesired tissue trauma. In a related embodiment, a conformable surface 14c can also be coupled to a deflecting mechanism described herein to allow the physician to remotely deflect or shape contact surface 14 to a shape ~~to~~ that at least partially matches that of a selected target tissue surface 5s or otherwise facilitates

positioning of surface 14 on target tissue surface 5s. This embodiment solves the problem of allowing the physician to position surface 14 when the target tissue surface 5s is obstructed by tissue and anatomical structures or is otherwise in a difficult position to reach.

On page 21, please replace the paragraph starting on line 12 with the following:

As shown in Figures 12a and 12b, in related embodiments the porosity of porous portions 14p can be used to control the flexibility stiffness of surface 14 by retaining greater or lesser amounts of fluid within section 14p to control its hydrostatic pressure (when the surface is coupled to a pressurized fluid delivery device such as an IV pump) and effectively inflate or deflate the section 14p (similar to an inflatable balloon) to a desired stiffness and shape. This can also be done by controlling the fluid pressure of the fluid delivery device 28 or fluid source 30 coupled to porous section 14p.

On page 22, please replace the paragraph starting on line 10 with the following:

Referring to Figure 14, apertures 14a in surface 14 can be configured to have a selectable angle, 14aa with respect to a longitudinal plane 14lp of tissue contact surface 14 such that electrode 18 ~~exist~~exits the aperture and enters into tissue at that angle. Angle 14aa can be in the range of 1 to 180° with specific embodiments of 30, 45, 60, 90, 120 and 135°.

On page 33, please replace the paragraph starting on line 14 with the following:

In an embodiment shown in Figure 30a, a conductivity enhancing solution 27 can be infused into target tissue site 5' including tissue mass 5". The conductivity enhancing solution can be infused before, during, or after the delivery of energy to the tissue site by the energy delivery device. The infusion of a conductivity enhancing solution 27 into the target tissue 5' creates an infused tissue area 5i that has an increased electrical conductivity (~~verses~~versus un-infused tissue) so as to act as an enhanced electrode 40. During RF energy delivery, the current densities in enhanced electrode 40 are greatly lowered allowing the delivery of greater amounts of RF power into electrode 40 and target

tissue 5' without impedance failures. In use, the infusion of the target tissue site with conductivity enhancing solution provides two important benefits: (i) faster ablation times; and (ii) the creation of larger lesions; both without impedance-related shut downs of the RF power supply. This is due to the fact that the conductivity enhancing solution reduces current densities and prevents desiccation of tissue adjacent the electrode that would otherwise result in increases in tissue impedance. A preferred example of a conductivity enhancing solution is a hypertonic saline solution. Other examples include halide salt solutions, ~~and~~ colloidal-ferro solutions, and colloidal-silver solutions. The conductivity of enhanced electrode 40 can be increased by control of the rate and amount of infusion and the use of solutions with greater concentrations of electrolytes (e.g. saline) and hence greater conductivity. In various embodiments, the use of conductivity enhancing solution 27 allows the delivery of up to 2000 watts of power into the tissue site impedance shut down, with specific embodiments of 50, 100, 150, 250, 500, 1000 and 1500 watts achieved by varying the flow, amount and concentration of infusion solution 27. The infusion of solution 27 can be continuous, pulsed or combinations thereof and can be controlled by a feedback control system described herein. In a specific embodiment, a bolus of infusion solution 27 is delivered prior to energy delivery followed by a continuous delivery initiated before or during energy delivery with energy delivery device 18 or other means.

On page 34, please replace the paragraph starting on line 19 with the following:

In an alternative embodiment, conductivity enhancing fluid 27 is injected by electrically non conductive needles or infusion members 18nci (which include lumens 72 and apertures 23) coupled to advancement member 16 and/or housing 12. Members 18nci can be coupled to a fluid delivery device 12fdd positionable within housing 12. Fluid 27 in members 18nci is electrically coupled to an RF or other power source 20 via a conductor or electrode 18c that is positioned within lumens 72 and 13 and electrically coupled to power source 20. Members 18nci are configured to infuse a fluid 27 into target tissue 5' to define a tissue infusion tissue volume 5i. Electrically non-conductive infusion member 18nci can be fabricated from a variety of polymers known in the art including

thermoset and rigid polymers such as ABS, acrylic and polycarbonate. Alternatively member 18nci can be fabricated from insulated metal using insulation materials described herein.

On page 35, please replace the paragraph starting on line 7 with the following:

In various embodiments, the conductivity of the tumor mass 5' can be enhanced so as to preferentially increase the rate and total amount of ~~energy~~ delivery of energy to the tumor mass 5' relative to healthy tissue. This can be achieved by infusing conductivity enhancing solution 27 directly into the tumor mass 5' through the use of a needle electrode 18 placed within the tumor mass only. In related embodiments solution 27 can be configured to remain or be preferentially absorbed or otherwise taken up by tumor mass 5". This can be achieved by controlling ~~by~~ one or more of the osmolality, viscosity and concentration of solution 27.

On page 35, please replace the paragraph starting on line 16 with the following:

As shown in Figure 30b apertures 23 can be also configured to provide cooling of electrodes 18 and surrounding tissue to prevent tissue desiccation and the deposition of charred tissue on the surface of electrode 18 and in turn, prevent the subsequent development of excessive impedance at or near electrode 18. The cooling is accomplished by both the use of a cooled solution to cool the electrodes by a combination of convection and conduction. The amount of cooling can be controlled by control of one or more of the following parameters: (i) temperature of the cooling solution; (ii) flow rates of the cooling solution; (iii) heat capacity (e.g. specific heat) of the cooling solution; and (iv) combinations thereof. Examples of cooling solutions include~~,~~ water, saline solution, ~~and~~ ethanol, and combinations thereof. Other embodiments can utilize a cooling fluid or gas 27g that serves to cool electrodes 18 by ebullient cooling or Joule-Thomson Effect cooling as well as the mechanisms described above. Embodiments utilizing Joule-Thomson Effect cooling can have a nozzle-shaped aperture 23n to provide for expansion of a cooling fluid 27g. Suitable cooling fluids 27g can include, but are not limited to, chilled water, freon, liquid CO_2, liquid nitrogen and other cryogenic gases.

On page 39, please replace the paragraph starting on line 20 with the following:

In other embodiments, at least a portion of sensors 22 can be pressure or force sensors positioned on or in housing 12, including tissue contact surface 14, so as to be able to measure the force applied by surface 14 onto tissue surface 5s and into target tissue site 5' tissue tumor mass 5". Additionally, pressure/force sensors can provide an indication of the size of the ablation volume and/or the degree of thermal injury due to the tissue shrinkage that occurs with the thermal contraction and denaturization of collagen comprising tumor mass 5" as well as the shrinkage/coagulation of the vasculature within the tissue mass. Thus, a decreased pressure on surface 5s can be an indication of the size of an ablation volume and/or the completeness of ablation of a tumor mass. Also, ~~in~~an increase in pressure could provide an indication as well, due to the development of steam and other gas pressure beneath tissue surface 5s. Measurement of pressure changes occurring during RF or other thermal ablation treatment described herein can be combined with temperature measurements to provide a more robust indication of complete tumor ablation and hence clinical endpoint. In one embodiment, an algorithm for determining an endpoint for ablation can include a polynomial equation and/or multi-variant analysis using both measurement of tissue temperature and tissue pressure as input parameters.

On page 42, please replace the paragraph starting on line 7 with the following:

Actuators 24" can include rocker switches, pivot bars, buttons, knobs, ratchets, cams, rack and pinion mechanisms, levers, slides and other mechanical actuators known in the art, all or portions of which can be indexed. These actuators can be configured to be mechanically, electro-mechanically, or optically coupled to pull wires, deflection mechanisms and the like allowing selective control and steering of introducer 12. Also actuators 24" can be configured such that longitudinal movement of actuators 24" is translated to a combination of lateral or longitudinal movement of electrodes 18, contact surface 14, or forceps 24p.

On page 43, please replace the paragraph starting on line 17 with the following:

In an embodiment shown in Figure 34, handpiece 24 including elongated portion 24e can include a bendable or deflectable portion 24b which is configured to allow portions of handpiece 24 to bend a selectable amount to allow the physician to position housing 12 on a selected surface of a target organ 5 including the posterior and lateral surfaces of the organ. In various embodiments, bendable portion 24b can comprise an articulated section using corrugated polymers known in the art or a section made from flexible or resilient materials including elastomers such as silicone or polyurethane, a coiled spring, a bendable wire, or a wire reinforced catheter. In a preferred embodiment, bendable portion 24b comprises a braided resilient polymer tube known in the art. Bendable portion 24b can be deflected using a number of deflection mechanisms known in the art including pull wires 15 and the like. Alternatively, for embodiments having ~~an~~ articulated bendable portions 24b, the articulations can have sufficient rigidity (e.g. bending force) to maintain its shape once the physician has bent it into a desired position. This can be achieved through the use of metallic or steel articulated sections 24b having bending force ranging from 0.5 to 10 lbs with specific embodiments of 1, 2.5 and 5 lbs of force.

On page 44, please replace the paragraph starting on line 9 with the following:

In other embodiments, handpiece 24 can be configured to not only position housing 12 adjacent the desired target tissue site, but also to shape or otherwise manipulate tissue contact surface 14 so as to at least partially conform contact surface 14 and/or housing 12 to the contour of the target tissue surface. This can be accomplished through a variety of mechanical means known in the surgical instrument arts. In an embodiment shown in Figure 35, this can be accomplished by a pull wire 15 (contained within elongated section 24e) attached in two or more places to a bendable tissue contact surface 14 and also to handpiece 24 so as to be controlled by actuators 24". In a related embodiment, it can be accomplished through the use of a forceps device 24f attached to tissue surface 14 and mechanically coupled to handpiece 24 (including actuator 24") by a connecting rod 15cr or pull wire 15. Actuator 24", connecting rod 15cr or pull wire 15 can be so configured such that a longitudinal movement of actuator 24 (with respect to axis 12al) is translated into lateral or curved movement of surface 14 relative to a plane 14p of surface 14. Forcep

device 24f can include forceps, curved forceps, hemostats, or any hinged or grasping device known in the surgical or mechanical arts.

On page 52, please replace the paragraph starting on line 11 with the following:

In various embodiments electrodes 18 can be operated in a monopolar mode, a bipolar mode, or a combination of both and can be switchable between the two. Referring now to Figure 43, when electrodes 18/apparatus 10 are operated in a monopolar mode, an indifferent electrode patch or ground pad 18g (also called a return electrode) is attached to the patient's skin using known methods (e.g. use of a conductive gel) and is also electrically coupled to power source 20 by a cable 20gc or other connecting means. Ground pad 18g serves to complete an electrical circuit between one or more electrodes 18, the tissue site 5' and the power source 20. Ground pad 18g can be a ground pad known in the art and can be made of a flexible material such as a resilient polymer and can include a smooth, texturized or ridged surface. Ground pad 18g has sufficient area to keep the current density at the point of contact with the patient ~~to~~ low enough to prevent any appreciable heating of the patient's skin. The ground pad can be an area in the range of 0.5 to 3 square feet, with specific embodiments of 1, 2, and 2.5 square feet. The use of a texturized or ridged surface serves to increase the amount of pad surface area in electrical contact with tissue and thus reduce current densities and reduce the risk of pad burns.

On page 61, please replace the paragraph starting on line 9 with the following:

Turning now to a discussion of the materials of apparatus 110, shaft member 112 and advancement member 116 can be fabricated from metals such as 304 stainless steel or Nitinol and the like or a rigid polymer such as a thermoset plastic, NYLON, ULTEM®, polyimide and the like. Also, all or portion of shaft 112 can have an insulative (both electrical and thermal) coating 113 which can include TEFLON®, polyimide, or silicone. Coating 113 can also be a lubricous coating such as TEFLON®, which serves to reduce the friction of moving components and tissue in contact with shaft 116. The interior of lumen 112l as well as advancement member 116 can also have coating 113. Similarly

advancement member 116 can have an insulative coating 113 which can be in the form of a movable sleeve 113s so as to expose and/or create an energy delivery surface 118s of electrode 118. Sleeve 113s can be mechanically linked to a coupled mechanical actuator 24" on handpiece 24 which can be coupled to shaft member 112. Struts 122 and 124 can be rigid or flexible and can be constructed from 304 or 304v stainless steel (for both rigid and flexible embodiments) and shaped memory metals such as Nitinol for flexible embodiments. Pivotal joints 121, 123 and 125 can be fabricated from machined or forged metals including 304 stainless steel and hardened tool steel. They can also include hinged, swaged, ball bearing or roller bearing pivot mechanisms known in the art. Guide tubes 128 can include rigid and flexible portions and can be fabricated from metal hypotubes which can be made from shape memory materials or high strength and/or resilient polymers such as polyimide, PEEK™, HDPE, (including radiated materials), PEBAX®, polyurethane and ULTEM®. Additionally, the distal portions 128d of guide tubes 128 can be more flexible than proximal portions 128p in order to assume a curved shape in the deployed state and then reassume a substantially linear shape in the non-deployed state. Accordingly the distal section 128d can be made from flexible polymers, such as polyurethane and or can have a smaller diameter ~~verses~~versus proximal portions 128p.